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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,127	02/06/2004	James M. Brugger	53951-119	8396
21890	7590	08/16/2007		
PROSKAUER ROSE LLP PATENT DEPARTMENT 1585 BROADWAY NEW YORK, NY 10036-8299			EXAMINER KIM, SUN U	
			ART UNIT 1723	PAPER NUMBER
			MAIL DATE 08/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,127	BRUGGER ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 29, 34, 40 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitation of “the ends of multiple tubular filter fibers” in claims 29 and 40 lacks a positive antecedent basis. Claims 29 and 40 are indefinite for failing to particularly point out whether “the outlet end cap” is a separate element from “the outlet cap”. For examination purposes, “the outlet end cap” is deemed the same as “the outlet cap”. Claims 34 and 45 are confusing since the outlet cap has a cylindrical portion and the outlet cap being removably connected to the cylindrical portion. Claims 34 and 45 need to clarify whether the outlet cap has separate end cap being removably connected to the cylindrical portion. For examination purposes, the outlet cap is the cylindrical portion.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 28-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,784,768 (hereinafter referred to as Mathieu). Mathieu teaches a filter apparatus comprising a cylindrical housing (1) having an interior volume separated by filter media of capillary fiber bundle (4, 5) into a filtrate part (10) or a treatment fluid volume and liquid part or liquid volume e.g. the internal lumens of capillary fiber bundle, the housing (1) including an outlet cap (2a) that defines a generally flat headspace in fluid communication with the liquid part wherein an outlet cap (2a) having two openings (3, 12), the housing (1) having a liquid port (3) connected to the first opening (3a) and a secondary port (12) connected to the second opening (12), the housing (1) having an outlet (11) in flow communication with the filtrate part and a blood inlet port (3) in communication with the liquid part wherein a gap (9) between filter media (4, 5) and the outlet cap (2a) forms a headspace and the outlet cap (2a) has an outlet port (3a) and additional port (12) that are open to the headspace and a gap (8) between filter media (4, 5) and the inlet cap (2) forms a headspace and the inlet cap (2) has an inlet port (3) and additional port (12) that are open to the headspace (see figure 1-3; col. 5, line 63 – col. 7, line 43). Mathieu further teaches that gas is supplied to the membranes via hydrophobic membrane (13, 13a) inherently through an additional port to liquid supply (see figure 1; col. 5, lines 11-20; 47-53). Such a gas supply through an additional port (12) to liquid supply or liquid extraction in the liquid inlet port (3) or liquid outlet port (3a) will be mixed in the headspace by sheer gap provided between the filter media and the cap. Claims 28-30, 35-37, 39-41 and 46 essentially differ from the filter apparatus of Mathieu in reciting that the blood port and the secondary port

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are not connected except through the headspace (claim 28), the only fluid channel connecting the blood and secondary ports includes the headspace as part of the fluid channel (claims 35, 46) and the outlet headspace of not more than 3 mm between the media and the outlet cap or in depth (claims 28, 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the filter apparatus of Mathieu to provide direct connection of the dilution inlet to the secondary outlet port in the outlet headspace in addition to blood outlet port for mixing of gas with liquid to gasify the liquid with oxygen as suggested by Mathieu (see col. 5, lines 11-20), since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Mathieu teaches inlet and outlet headspaces (8, 9) which is formed between the filter media (4, 5) and the outlet cap (2a) (see figure 1); however, Mathieu is silent as to the distance between the media and the outlet cap. A device having the claimed relative dimensions of the headspace by the distance between the media and the outlet cap would not perform differently than the device of Mathieu and the claimed device is not patentably distinct from the prior art device. See *In re Gardner v. Tec Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 225 USPQ 232 (1984); see MPEP 2144.04, IV. A.

Recitations of “such that blood can leave the headspace through the first opening while fluid is simultaneously injected into the headspace through the second opening” in claim 36 and “such that blood can leave the headspace through the first opening while fluid is simultaneously injected into the headspace through the second opening, and the fluid is thoroughly mixed with the blood before the blood leaves the headspace” in claim 37 and “such that blood is able to leave the outlet headspace while fluid is simultaneously injected into the outlet headspace” in

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claim 39 are an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The structural elements capable of performing above functions should be clearly claimed rather than a general recitation of the configurations of the first and second openings.

Use of the ports as an inlet and/or outlet for different fluids are an intended use of the apparatus and these are not given patentable weight to the structural limitation without the positive recitation of the specific fluid source e.g. blood, specific fluid, etc. connected to specific ports.

Regarding claims 31 and 42, Mathieu shows that the first opening (3a) is larger than the second opening (12) (see figure 1).

Regarding claims 32-33 and 43-44, Mathieu teaches that the first opening (3a) is aligned with the longitudinal axis of the housing (1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the filter apparatus of Mathieu to provide the second opening remote from the longitudinal axis so long as intended fluid is supplied to the outlet headspace for mixing of gas with liquid to gasify the liquid with oxygen as suggested by Mathieu (see col. 5, lines 11-20), since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding claims 34 and 45, Mathieu teaches that the cylindrical end caps (2a) are fitted in sealing manner to a housing body (1) which are inherently removably attached to the housing body (1) (see Fig. 1; col. 5, lines 64-67; col. 7, lines 65-66).

Regarding claim 38, Mathieu teaches that the outlet cap (2a) has a wall defining a portion of the headspace and the openings (3, 12) are in the wall facing the headspace (9) (see figure 1).

5. Applicant's arguments with respect to claims 28-46 have been considered but are moot in view of the new ground(s) of rejection. Applicants argue that why a person of ordinary skill would have had a reason to modify the device of Mathieu. Mathieu teaches that an additional port or tubular supply connecting piece is provided to the headspace for mixing of gas with liquid to gasify the liquid with oxygen as suggested by Mathieu (see col. 5, lines 11-20; col. 6, lines 38-57).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/John Kim/
Primary Examiner, Art Unit 1723**

JK
8/14/07